VALIDATION

Note: The WCSO DNA Unit follows the current FBI Quality Assurance Standards to fulfill the components of each validation study, in addition to the criteria referenced in Doc. I.D. 856.

STANDARD 8.1

The Washoe County Sheriff's Office (WCSO) DNA Section uses Real-time PCR for DNA quantitation and the PCR method to amplify Short Tandem Repeat (STR) regions of DNA. The quantitation, STR and Y-STR methods have been validated developmentally and internally prior to using them on casework. Refer to the DNA Procedure Manual and WCSO internal validation studies for additional information.

STANDARD 8.2

Developmental validation of Plexor HY with Real-time PCR for DNA quantitation was completed by Promega. Developmental validation of DNA analysis at STR regions was completed by Promega (PowerPlex 16 HS) Applied Biosystems (GlobalFiler and YFiler).

STANDARD 8.3

The WCSO DNA Section has completed internal validation studies.

Qiagen extraction was internally validated on 5/8/02.The validation of this system was reviewed during an external annual audit according to the Federal Standards by Stephanie Rauscher-Finn on 1/23/05 -1/25/05 and again by Cynthia Hall on 12/14/05 -12/16/05.

Y chromosome analysis utilizing the YFiler kit with both a CE310 and a CE3130 was internally validated on 6/14/06. These validations were reviewed during an external annual audit according to the Federal Standards by Jim Iverson and Ann Marie Gross on 11/14/07-11/16/07.

Four Eppendorf Mastercycler Ep Thermal Cyclers were internally validated on 4/13/09 for use on casework and Convicted Offender samples. The validations of these systems were reviewed during an external annual audit according to the Federal Standards by Kim Murga, Kathy Guenther, and Julie Marschner on 12/15/09 - 12/17/09.

The PowerPlex 16 HS amplification kit was internally validated using a CE3130 on 02/16/10 for use on casework and Convicted Offender samples. The Plexor HY quantification kit was internally validated using an ABI 7500 Real Time PCR unit on 2/16/2010. The validations of these systems were reviewed during an external annual audit according to the Federal Standards by Jonathan Newman and Deanna Lankford on 3/9/10 - 3/12/10.

Genemapper ID-X was internally validated on 6/29/10. This validation was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

One QIAcube Extraction robot (serial #6980) was internally validated and three additional QIAcubes (serial #7909, 7918, and 7920) performance checked on 10/4/10. This testing was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

The Eppendorf's Temperature Verification System (multi-probe) was internally validated for use on the Eppendorf Mastercycler Ep Thermal Cyclers and the Eppendorf Mastercycler Pro Thermal Cyclers (Mastercycler Pro validation in process) on 1/28/11. This validation was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

The Testo 950 Temperature Verification System (single-probe) was internally validated for use on the Eppendorf Mastercycler Ep Thermal Cyclers and the Eppendorf Mastercycler Pro Thermal Cyclers (Mastercycler Pro validation in process) on 7/15/11. This validation was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

The elimination of the re-quantitation of samples post microcon concentration was internally validated on 1/28/11. This validation was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

The performance check of 7500-C real time PCR instrument was completed on 1/5/11. This performance check was reviewed during an external annual audit according to the Federal Standards by Pamela Mikulcik, Kimberly Wilutis, and Robin Rothove on 11/7/11-11/9/11.

The performance check of Popstats as part of CODIS 7 was completed on 5/25/12. This performance check was reviewed during an external audit according to the Federal Standards by Sandy Shaffer and Hayne Hamilton on 11/5/13-11/8/13.

The validation of Whatman EasiCollect device was completed on 7/16/12. This validation was reviewed during an external audit according to the Federal Standards by Sandy Shaffer and Hayne Hamilton on 11/5/13-11/8/13.

The validation of the Fast Flow Microcons was completed on 9/10/12. This validation was reviewed during an external audit according to the Federal Standards by Sandy Shaffer and Hayne Hamilton on 11/5/13-11/8/13.

The validation of the four Eppendorf Mastercycler Pro thermalcyclers was completed on 3/18/13. This validation was reviewed during an external audit according to the Federal Standards by Sandy Shaffer and Hayne Hamilton on 11/5/13-11/8/13.

The performance check of the ThermoMixers was completed on 2/26/14. This performance check was reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15.

The validation of the epMotion 5075 liquid handling robot for capillary electrophoresis setup was completed on 3/13/14. The validation of this system was reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15.

The performance check of the GeneMapper ID-X software upgrade to version 1.4 was completed on 5/1/14 (including the 6-dye upgrade). This performance check was reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15 and by Jennifer Mihalovich, Tuan Nguyen, Stephen Gicale, and Kris Cano on 10/24/17 – 11/6/17.

The performance check of the Plexor Analysis software upgrade to version 1.5.6.7 was completed on 4/23/14. This performance check was reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15.

The performance check of the CODIS 7.0 Service Pack 4 and CODIS 7.0 Service Pack 5 software upgrades were completed on 10/2/14 and 6/19/15, respectively. These performance checks were reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15.

The validation of the epMotion 5075 liquid handling robot for quantitation set-up, normalization and amplification setup was completed on 9/10/15. The validation of this system was reviewed during an external annual audit according to the Federal Standards by Jessica Charak, Cassandra Robertson and Julie Marschner on 10/19/15-10/20/15. Note: Analyst competency testing had not yet been completed for all analysts at the time of this audit.

The validation of the NIST population database with Popstats for calculating profile frequency was completed on 2/18/16 with the Performance check of the updated NIST Population Database from 2017 being completed on 8/23/2017. These were reviewed during an external annual audit according to the Federal Standards by Jennifer Mihalovich, Tuan Nguyen, Stephen Gicale, and Kris Cano on 10/24/17 – 11/6/17.

The validation of the GlobalFiler amplification kit for use on casework and offender samples was completed on 3/1/16 and reviewed during an external annual audit according to the Federal Standards by Jennifer Mihalovich, Tuan Nguyen, Stephen Gicale, and Kris Cano on 10/24/17 – 11/6/17.

The performance check of the WCSO DNA Section mixture interpretation guidelines for data generated with PowerPlex 16 HS was completed on 3/1/16.

8.3.1 The internal validation studies include as applicable: known and non-probative evidence samples or mock evidence samples, reproducibility and precision, sensitivity and stochastic studies, mixture studies, and contamination assessment. Internal validation studies are documented and summarized.

8.3.2 Interpretation guidelines were established based on the internal validation studies. These along with the quality assurance parameters are detailed in the WCSO DNA Procedure Manual.

STANDARD 8.4

Each analyst completed competency testing prior to the use of a newly validated technique.

STANDARD 8.5

Performance of a modified procedure is evaluated by comparison with the original procedure using similar DNA samples. Modifications must be documented and approved by the Technical Leader.

STANDARD 8.6

Each new critical instrument or software upgrade requires a performance check. Modifications to an instrument, such as a detection platform, that do not affect the analytical portion of the instrument require a performance check, i.e., upgrade of instrument model. A change in software that would impact interpretation, the analytical process, or sizing algorithms shall require a validation prior to implementation.